

corrected sheet

PATENT COOPERATION TREATY

OMM

PCT

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference 227	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/KR 2004/002590	International filing date (day/month/year) 11 October 2004 (11.10.2004)	Priority Date (day/month/year) 10 October 2003 (10.10.2003)
International Patent Classification (IPC) or national classification and IPC IPC <sup>8</sup> : A61K 31/56 (2006.01)		
Applicant SK CHEMICALS CO. LTD.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examination Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of <u>4</u> sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e., sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 10.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of _____ sheets.</p> <p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none"><li>I. <input checked="" type="checkbox"/> Basis of the opinion</li><li>II. <input type="checkbox"/> Priority</li><li>III. <input type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicability</li><li>IV. <input type="checkbox"/> Lack of unity of invention</li><li>V. <input checked="" type="checkbox"/> Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement</li><li>VI. <input checked="" type="checkbox"/> Certain documents cited</li><li>VII. <input type="checkbox"/> Certain defects in the international application</li><li>VIII. <input type="checkbox"/> Certain observations on the international application</li></ul>		

Date of submission of the demand 28 April 2005 (28.04.2005)	Date of completion of this report 28 March 2006 (28.03.2006)
Name and mailing address of the IPEA/AT Austrian Patent Office Dresdner Straße 87 A-1200 Vienna Facsimile No. 1/53424/200	Authorized officer KRENN M. Telephone No. 1/53424/435

Form PCT/IPEA/409 (cover sheet) (July 1998)

BEST AVAILABLE COPY

**INTERNATIONAL PRELIMINARY EXAMINATION REPORT**

International application No.  
PCT/KR 2004/002590

**I. Basis of the report**

1. With regard to the elements of the international application:\*

the international application as originally filed

the description:

pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

the claims:

pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, as amended (together with any statement) under Article 19  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

the drawings:

pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

the sequence listing part of the description:

pages \_\_\_\_\_, as originally filed  
pages \_\_\_\_\_, filed with the demand  
pages \_\_\_\_\_, filed with the letter of \_\_\_\_\_

2. With regard to the language, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language \_\_\_\_\_ which is:

the language of a translation furnished for the purposes of international search (under Rule 23.1(b)).

the language of publication of the international application (under Rule 48.3(b)).

the language of the translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any nucleotide and/or amino acid sequence disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

contained in the international application in printed form.

filed together with the international application in computer readable form.

furnished subsequently to this Authority in written form.

furnished subsequently to this Authority in computer readable form.

The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4.  The amendments have resulted in the cancellation of:

the description, pages \_\_\_\_\_.

the claims, Nos. \_\_\_\_\_.

the drawings, sheets/fig. \_\_\_\_\_.

5.  This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed, as indicated in the Supplemental Box (Rule 70.2(c)).\*\*

\* Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as „originally filed“ and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17).

\*\* Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.  
Form PCT/IPEA/409 (Box I) (July 1998))

**BEST AVAILABLE COPY**

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/KR 2004/002590

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement		
I. Statement		
Novelty (N)	Claims —	YES
	Claims 1-5	NO
Inventive step (IS)	Claims —	YES
	Claims 1-5	NO
Industrial applicability (IA)	Claims 1-5	YES
	Claims —	NO
Citations and explanations (Rule 70.7)		

D1: CHUNG et al., "Inhibitory effect of ursolic acid purified from *Origanum majorana* L. on the acetylcholinesterase.", *Molecules and Cells*, 30 Apr. 2001, Vol. 11(2), pp. 137-143

D2: HEO et al., "Ursolic acid of *Origanum majorana* L. reduces Abeta-induced oxidative injury", *Molecules and Cells*, 20 Feb. 2002, Vol. 13(1), pp. 5-11

D3: KR 2003-0042123 A (KOREA RESEARCH INSTITUTE OF BIOSCIENCE AND BIOTECHNOLOGY) 28 May 2003

D4: SHIN et al., "Ursolic acid protects hippocampal neurons against kainite-induced excitotoxicity in rats.", *Neuroscience Letters*, 20 May 2004, Vol. 362(2), pp. 136-140

D5: KITANI et al., "Pharmacological modifications of endogenous antioxidant enzymes with special reference to the effects of deprenyl: a possible antioxidant strategy", *Mechanisms of Ageing and Development*, Nov. 1999, Vol. 111(2-3), pp. 211-221

D6: US 6607758 B2

D7: US 2002/0042535 A1

The subject matter of claims 1-5 (= first medical use claims) is anticipated by D1 and D2, which refer to the use of ursolic acid (= one of the presently claimed compounds) in medicine.

The relevance of D3 is not understood, because it refers to the use of tiarelic acid, which structurally differs from the compounds presently claimed.

After filing of the priority document D4, which was published within the priority term, is not anymore a relevant document.

Furthermore, the classification of D5 as "A"-document is not comprehensible, because it discusses the pharmacological activity of ursodeoxycholic acid resp. ursolic acid; the latter is claimed in the present application.

D6 discloses a method of inhibiting amyloid formation consisting in the administration of a therapeutically effective amount of plant matter from a plant of the genus *Uncaria*.

D7 refers to a steroid compound, which can be used for the treatment of cancer, neurodegenerative diseases, etc..

Consequently, in respect to D1, D2 and D5 claims 1-5 are neither new nor inventive.

Industrial applicability is given.

## INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No.  
PCT/KR 2004/002590

## VI. Certain documents cited

## 1. Certain published documents (Rule 70.10)

Application No. Parent No.	Publication date (day/month/year)	Filing date (day/month/year)	Priority date (valid claim) (day/month/year)
-------------------------------	--------------------------------------	---------------------------------	---

SHIN et al., "Ursolic acid protects hippocampal neurons against kainite-induced excitotoxicity in rats.", Neuroscience Letters, 20 May 2004

## 2. Non-written disclosures (Rule 70.9)

Kind of non-written disclosure	Date of non-written disclosure (day/month/year)	Date of written disclosure referring to non-written disclosure (day/month/year)
--------------------------------	--	---